Empi

PHOENIX™

COMPLETE ELECTROTHERAPY SYSTEM

USER'S MANUAL

- Read this manual carefully before operating the Phoenix™
- Visit us at www.djoglobal.com

Empi®

Table of Contents

1. Foreword 4

2. Intended Use 5

2.1 Indications for Use 5
2.2 Use Environment 5

3. Explanation of Symbols 6

4. Safety Information 7

4.1 Contraindications 7
4.2 Warnings 7
4.3 Precautions 8
4.4 Dangers 10
4.5 Adverse Reactions 10

5. How Does Electrotherapy Work? 11

6. Usage Guidelines 12

6.1 Program Descriptions 12
6.1.1 Endurance – P1 12
6.1.2 Strength – P2 13
6.1.3 Modulated TENS – P3 14
6.1.4 Edema – P4 14
6.2 Choice of the Appropriate Program 14
6.3 Planning of Stimulation Sessions 15
6.4 Electrode Positions 15
6.4.1 Use of the Empi Phoenix Thigh Garment 15
6.5 Stimulation Positions 16
6.6 Adjusting Stimulation Energies 16

7. Operating Instructions 17

7.1 Description of the Device 17
7.2 Kit Composition and Accessories Description 18
7.3 Preparation 19
7.3.1 Insertion/replacement of the batteries 19
7.3.2 Connection of the lead wires to the device 19
7.3.3 Placement and care of the electrodes 20
7.3.4 Connection of the lead wires to the electrodes 20
7.3.5 Use of the Empi Phoenix Thigh Garment (optional) 20
7.4 Operation of the Device 21
7.4.1 LCD Display 21
7.4.2 Operation Information 21
7.4.3 Operating Instructions 21
7.4.4 Pause Function 22
7.4.5 End of Treatment 22
7.4.6 Use of the Hand Switch (optional) 22

7.5 Meaning of Indicators 23
7.5.1 Intensity Lock 23
7.5.2 Sequence Indicator 23
7.5.3 Work/Rest Indicator 23
7.5.4 Timer Indication 23
7.5.5 Low Battery Indicator 23
7.5.6 Open Circuit Icon 23

8. Troubleshooting 24

9. Device Maintenance 26
9.1 Service 26
9.2 Cleaning and Calibration 26
9.3 Repair 27
9.4 Operating Conditions 27
9.5 Transportation and Storage Conditions 27
9.6 Expected Life and Disposal 27

10. Ordering Information 28

11. Clinician Only Section 28
11.1 Compliance Monitoring 28
11.2 Program Lock 29
11.3 Ordering Information for Clinicians 29

12. Limited Warranty 29

13. Technical Specifications 32

14. Guidance and Manufacturer's Declaration – Electromagnetic Emissions 34

15. Additional Information on Electrode Placement for Knee Treatment 38

16. Quick Start Guide 39

1. Foreword

The Empi Phoenix is a multifunctional electrotherapy device that provides two channels of neuromuscular electrical stimulation (NMES), transcutaneous electrical stimulation (TENS), or pulsed DC (Edema treatment). This wide-ranging capability allows the patient to receive electrotherapy throughout the recovery cycle using a single device. Its simplified programming makes the device convenient for home use: after placing the electrodes and selecting the program as prescribed by a healthcare professional, the patient only needs to increase the intensity to begin therapy.

The Phoenix device's NMES Endurance and Strength programs utilize an electrical stimulus that, when properly applied, activates specific muscles or muscle groups to help treat disuse atrophy and re-educate muscles. The pre-set programs are designed to provide therapeutic benefit while minimizing complexity for the patient and clinician. The device can be paired with the Empi Phoenix Conductive Garment for the thigh, which is designed to make treatment of the knee/quadriceps with NMES easier for the patient and clinician.

The Phoenix device also includes a traditional TENS program for pain management and a pulsed DC Edema program to increase local blood circulation and reduce edema (swelling).

Read this User Manual carefully before using the Phoenix device. Pay particular attention to the Safety Information in Section 4 and additional warnings throughout the manual.

℞ Only **Caution:** Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

2. Intended Use

2.1 Indications for Use

As an NMES device, indications are for the following conditions:

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles
- Relaxation of muscle spasms
- Increasing local blood circulation

As a TENS device, indications are for the following conditions:

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

As a pulsed current device, indications are for the following conditions:

- Reduction of edema (under negative electrode)
- Reduction of muscle spasm
- Influencing local blood circulation (under negative electrode)
- Retardation or prevention of disuse atrophy
- Facilitation of voluntary motor function
- Maintenance of increase of range of motion

2.2 Use Environment

The Empi Phoenix device is a prescription device in the USA and is intended to be used following the directions of a healthcare provider. The device should be used indoors and may be used in a healthcare facility setting or by a patient or lay operator in a home environment.

3. Explanation of Symbols

The following symbols are used either in this user manual, on the device packaging, or on the device label. They may also appear on an accessory.

Symbol	Explanation
REF	Reference number; part number
LOT	Lot number
	Follow instruction for use
	Type BF applied parts
	Keep the device dry
	Keep the device away from sunlight
IP22	Protected against solid foreign objects of 12.5 mm (0.5 in) diameter and greater Protected against vertically falling water drops when enclosure tilted up to 15°
	Minimum and maximum temperature indications to respect
	Prescription only (USA)
	ETL Classified C US, 9900900, Electronic Testing Lab, indicates product meets US and Canadian product safety standards. This device Conforms to AAMI Std. ES60601-1. Certified to CAN/CSA Std. C22.2#60601-1.
	Manufacturing year
	Manufacturer name and address
	Power/Pause
	Dangerous voltage
	Lead wires comply with the Performance Standard for electrode lead wires (21 CFR part 898)

4. Safety Information

This section includes Contraindications, Warnings, Precautions, Dangers, and Adverse Reactions.

4.1 Contraindications

Implanted electronic devices. Do not use the Empi Phoenix device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted electronic device, because this may cause electric shock, burns, electrical interference, or death.

TENS for undiagnosed pain. Do not use the Empi Phoenix device as a TENS device (P3) on patients whose pain syndromes are undiagnosed.

4.2 Warnings

Consult with physician. Consult with the patient's physician before using the Empi Phoenix device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.

Skin condition. Apply stimulation only to normal, intact, clean, healthy skin.

Long term effects. The long-term effects of chronic electrical stimulation are unknown.

Stimulation location

Stimulation over neck or mouth. Do not apply stimulation over the patient's neck (especially the carotid sinus) or the patient's mouth, because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

Stimulation across chest. Do not apply stimulation across the patient's chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.

Across the head. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.

Stimulation over compromised skin. Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).

Stimulation near cancerous lesions. Do not apply stimulation over, or in proximity to, cancerous lesions.

Stimulation over metallic implants. Do not apply stimulation directly over implanted metallic devices, because this may cause shock or burns.

Stimulation over eyes. Do not apply stimulation directly on the eyes.

Environment

Electronic monitoring equipment. Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.

Bath or shower. Do not apply stimulation when the patient is in the bath or shower. Do not apply stimulation in humid atmosphere exceeding 75% of relative humidity.

Sleeping. Do not apply stimulation while the patient is sleeping.

Driving or operating machinery. Do not apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation or involuntary muscle contraction can put the patient at risk of injury.

Electrosurgical equipment or defibrillators. Disconnect the Empi Phoenix stimulation electrodes before using electrosurgical equipment or defibrillators. Otherwise skin burns may be caused below the electrodes and the Empi Phoenix device might be destroyed.

Magnetic Resonance Imaging. Do not wear electrode or the Empi Phoenix device during Magnetic Resonance Imaging (MRI) scans as this may result in metal overheating and causing skin burns in the area of the electrode.

Flammable or explosive environment. Do not use the Empi Phoenix device in areas where there is a risk of fire or explosion, such as oxygen-rich environments, in the vicinity of flammable anaesthetics, etc.

Power supply. Never connect stimulation cables to an external power supply as there is a risk of electric shock.

Near other equipment. Do not use the Empi Phoenix device beside or stacked on top of any other equipment. If you must use it side by side or on top of another system, you should check that the Empi Phoenix device works properly in the chosen configuration.

Miscellaneous

Garment and electrodes for single patient. Do not share electrodes or garments with other persons. All users should have individual set of electrodes to prevent undesirable skin reactions or disease transmission.

Accessories. Use this device only with the leads, electrodes, and accessories recommended by Empi. Use of other accessories may adversely affect the performance of the device or may result in stronger electromagnetic emissions or reduce the electromagnetic immunity of the Empi Phoenix device.

No Modification. No modification of the equipment is allowed.

4.3 Precautions

Supervision. Use this device only under the continued supervision of a licensed practitioner. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

Pregnancy. The safety of electrical stimulation during pregnancy has not been established.

Skin irritation. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel). The irritation may be reduced by using an alternate conductive medium or alternate electrode placement. Some patients may experience redness under the electrodes after a session. This redness usually disappears within a few hours. Advise the patient to consult the clinician if the skin redness does not disappear after a few hours. Do not start another stimulation session in the same area if the redness is still visible. Don't scratch the redness area.

Heart disease. Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.

Epilepsy. Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.

Internal bleeding. Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture.

After surgery. Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process.

Over uterus. Use caution if stimulation is applied over the menstruating or pregnant uterus.

Lack of sensation. Use caution if stimulation is applied over areas of skin that lack normal sensation. Don't apply stimulation on patient unable to express themselves.

Hot casing or batteries. Under extreme use conditions, some parts of the casing might reach up to 109 °F (43 °C). Use caution when manipulating the batteries right after device use or when holding the device. There is no particular health risk associated with this temperature besides your comfort.

Children. Keep this device out of the reach of children.

Electrode size. Do not use electrodes with an active area less than 16 cm^2, as there will be a risk of suffering a burn injury. Caution should always be exercised with current densities more than 2mA/cm^2.

Strangulation. Do not wrap leadwires around your neck, and keep them out of the reach of children. Strangulation may result from entanglement in the leadwires.

Tripping. Care should be used to avoid tripping on lead wires.

Damaged device or accessories. Never use the Empi Phoenix device or any of its accessories if it is damaged (case, cables, etc.) or if the battery compartment is open as there is a risk of electric shock. Carefully inspect the lead wires and connectors prior to each use.

Inspect electrodes. Inspect electrodes before each use. Replace electrodes when they begin to deteriorate or lose adhesion. Poor contact between the electrodes and the patient's skin increases the risk of skin irritation or burns. Electrodes will last longer if used and stored according to instructions on electrode packaging. Attach the electrodes in such a way that their entire surface is in contact with the skin.

Foreign bodies. Do not allow any foreign bodies (soil, water, metal, etc.) to penetrate the Empi Phoenix device and the battery compartment.

Garment. Do not use the Empi Phoenix Thigh Garment in proximity of fire or excessive heat sources due to the risk of fire. Make sure that the electrodes cover the metal connectors on the Phoenix garment before use to avoid shocking, skin irritation, and burns.

Batteries. Do not carry batteries in a pocket, purse, or any other place where the terminals could become short-circuited (e.g. by way of paper clip). Intense heat could be generated and injury may result.

Heat and cold products. The use of heat or cold producing devices (e.g. electric heating blankets, heating pads or ice packs) may impair performance of the electrode or alter the patient's circulation/sensitivity and increase the risk of injury to the patient.

Pulled muscles. Do not apply electrodes over pulled muscles. Using the stimulator on a previously extended muscle might further pull such muscle. The higher the stimulation intensity, the higher the risk to further overextend such muscle.

DC Component. The Empi Phoenix waveforms may contain a DC component (only for Edema program P4). Always use Empi electrodes with a minimum active area of 16 cm^2 (including Empi square (2" x 2") StimCare electrodes). Use of an electrode with an area less than 16 cm^2 can cause burns when the unit is used at higher intensities. Consult your clinician prior to using any electrode less than 16 cm^2.

This DC component for the Edema program (P4) is equivalent to 266 µA DC for all intensities above 4 mA.

Additional Precautions for TENS (P3)

- TENS is not effective for pain of central origin, including headache.
- TENS is not a substitute for pain medications and other pain management therapies.
- TENS devices have no curative value.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- Effectiveness of TENS is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.

4.4 Dangers

Electrodes. Any Empi Electrode with a minimum active area of 16 cm^2 may be used with this device. This includes Empi 2" round and 2" square StimCare electrodes. Use of an electrode with an area less than 16 cm^2 can cause burns when the unit is used at higher intensities. Consult your clinician prior to using any electrode less than 16 cm^2.

Dangerous voltage. Stimulus delivered by the waveforms of the Phoenix device, in certain configurations, will deliver a charge of up to 20 microcoulombs (μC) or greater per pulse and may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.

4.5 Adverse Reactions

- Patients may experience **skin irritation and burns** beneath the stimulation electrodes applied to the skin.
- Patients may experience **headache and other painful sensations** during or following the application of electrical stimulation near the eyes and to the head and face.
- Patients should **stop using the device** and should consult with their physicians if they experience adverse reactions from the device.

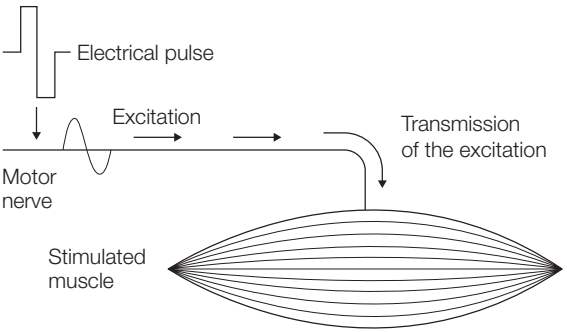
5. How Does Electrotherapy Work?

The principle of electrotherapy is to stimulate nerve fibers by means of electrical impulses transmitted by electrodes. The NMES electrical pulses generated by the Empi Phoenix stimulators are high-quality pulses that have been clinically tested and offer safety, comfort, and efficiency. These electrical pulses can:

- Stimulate motor points of target muscles, causing a muscle contraction. This can help re-educate and strengthen your muscles following an injury or surgery. This is called neuromuscular electrical stimulation (NMES). The Empi Phoenix programs P1 and P2 are NMES programs.
- Manage pain. The electrical pulses block the pain signal sent from the affected area on your nerve pathways. This is called the “Gate Theory” of pain control, and this form of electrotherapy is called transcutaneous electrical nerve stimulations (TENS). The Empi Phoenix program P3 is a TENS program.
- Increase local blood circulation, helping to reduce swelling or edema. The electrical current can affect the movement of fluid through tissue, and increasing blood flow can help increase healing. This therapy can be achieved using a pulsed direct current. The Empi Phoenix program P4 is a pulsed, direct-current program.

During voluntary activity, the brain sends a command to the nerve fibers in the form of an electrical signal to give the order to move. This signal is then transmitted to the muscular fibers, which contract. The principle of electrotherapy emulates the process observed during a voluntary contraction. In other words, the muscle cannot distinguish whether the command comes from the brain or from the stimulator. The parameters of the Empi Phoenix programs (number of pulses per second, contraction time, rest time, total program time) subject the muscles to different types of work.

In fact, different types of muscular fibers may be distinguished according to their respective contraction speed: slow, intermediate, and fast fibers. Fast fibers would predominate in a sprinter, while a marathon runner would likely have more slow fibers. With a good knowledge of human physiology and well-designed stimulation programs, muscular work can be directed very precisely towards the desired goal (muscular re-education, relaxation of muscle spasm, pain management, increased blood flow, maintaining, or increasing range of motion, etc.)



Elementary Mechanical Response - Twitch

6. Usage Guidelines

6.1 Program Descriptions

The choice of a program is determined by the injured body parts or joints. The appropriate stimulation programs (e.g., Endurance, Strength, TENS, or Edema) and frequency of the program(s) are determined by the medical professional. Consult your medical professional to be sure to understand the Empi Phoenix device.

6.1.1 Endurance – P1

The Empi Phoenix Endurance program focuses on generating a medium muscle contraction. This working level is maintained over a long time period (20 minutes per session). The Endurance program specifically activates the aerobic metabolism of the fibers during the stimulation session. The purpose is to increase the time for the muscle to maintain a medium contraction or the average power level for extended periods of time. This program is recommended for use before and after the surgery as prescribed by your medical professionals.

P1 begins with a two-minute Warm-Up phase, which will count down on the screen. The Warm-Up phase will cause your muscles to twitch but not contract. Set the device intensity to a comfortable level during Warm-Up. Once the Work phase begins, the intensity will automatically decrease by half. You can then adjust the intensity to provide a comfortable but strong muscle contraction. The program finishes with a Cool-Down phase similar to the Warm-Up phase.

ENDURANCE (P1)	
Waveform	Symmetrical square biphasic asynchronous
WARM UP	SETTING
Treatment time	2 min
Cycling type	Continuous
Pulse duration	300µs
Frequency - warm up	6 Hz
WORK PHASE	SETTING
Treatment time	15 min
Cycling type	Intermittent
Pulse duration	300µs
Frequency - work	35 Hz
Frequency - rest	4 Hz
Work time	6 sec
Rest time	7 sec
Ramp up time work	1.5 sec
Ramp down time work	0.75 sec
Ramp up time rest	0.5 sec
Ramp down time rest	0.5 sec

COOL DOWN	SETTING
Treatment time	3 min
Cycling type	Continuous
Pulse duration	300µs
Frequency – cool down	3 Hz

6.1.2 Strength – P2

The Empi Phoenix Strength program imposes a high and instantaneous power working level on muscle fibers. These contractions are separated by long periods of rest. The result is an average medium power working level (+ 20 minutes). This program is intended to increase the maximum strength of muscle isometric contraction. This program targets the muscle fibers that are typically afflicted with immediate atrophy after injury or/and surgery.

P2 begins with a two-minute Warm-Up phase, which will count down on the screen. The Warm-Up phase will cause your muscles to twitch but not contract. Set the device intensity to a comfortable level during Warm-Up. Once the Work phase begins, the intensity will automatically decrease by half. You can then adjust the intensity to provide a comfortable but strong muscle contraction. The program finishes with a Cool-Down phase similar to the Warm-Up phase.

STRENGTH (P2)	
Waveform	Symmetrical square biphasic asynchronous
WARM UP	SETTING
Treatment time	2 min
Cycling type	Continuous
Pulse duration	300µs
Frequency - warm up	6 Hz
WORK PHASE	SETTING
Treatment time	15 min
Cycling type	Intermittent
Pulse duration	300µs
Frequency - work	75 Hz
Frequency - rest	4 Hz
Work time	4 sec
Rest time	10 sec
Ramp up time work	1.5 sec
Ramp down time work	0.75 sec
Ramp up time rest	0.5 sec
Ramp down time rest	0.5 sec
COOL DOWN	SETTING
Treatment time	3 min
Cycling type	Continuous
Pulse duration	300µs
Frequency – cool down	3 Hz

6.1.3 Modulated TENS – P3

This treatment is a modulated TENS program for the treatment of post-surgical or chronic pain. Use this program with direct lead wires and electrodes (included in the device box), **not** with the garment. Place the electrodes around the site of the pain.

TENS	
PARAMETER	SETTING
Waveform	Symmetrical square biphasic asynchronous, frequency modulated
Treatment time	Unlimited*
Cycling type	Continuous
Pulse duration	80µs
Frequency 1	120 Hz
Frequency 2	90 Hz
Modulation time	4 sec

* “Unlimited” means that the timer does not automatically stop the treatment after a set time.

6.1.4 Edema – P4

This treatment option is a sequenced, net positive DC 2-channel program for edema reduction and increased circulation. For acute Edema (less than 48 hours post-injury or post-op), place the positive electrodes over the treatment site and attach the negative leadwire pins to the dispersive pad. For chronic Edema (no immediate prior injury/surgery or more than 48 hours post-injury or post-op), place the negative electrodes over the treatment site and attach the positive leadwire pins to the dispersive pad.

EDEMA	
PARAMETER	SETTING
Waveform	Net positive pulsed DC
Treatment time	30 min
Cycling type	Continuous
Pulse duration	60-120 Hz
Frequency	222Hz

6.2 Choice of the Appropriate Program

The choice of a program is determined by your clinician based on the affected body part(s). The appropriate muscle stimulation program(s) (e.g., Strength, Endurance, TENS or Edema) and frequency of the program(s) are determined by your clinician. Consult your Clinician or therapist if you are unsure which program to use.

6.3. Planning of Stimulation Sessions

Your clinician will instruct you on a protocol (intensity, electrode placement, number of times per day and per week) to follow in order to use the Empi Phoenix device most effectively.

6.4 Electrode Positions

For optimal results, use the electrode positions recommended by your medical professional. Please also refer to the pictures and pictograms shown at the bottom of this section. For best results, wash and clean the skin and dry it before attaching the electrodes.

Each stimulation cable has two pins:

A positive pin (+) = red connection
A negative pin (-) = black connection

An electrode should be connected to each pin. Always follow your clinician's instructions about electrode connection and application. Attach the electrodes in such a way that their entire surface is in contact with the skin.

Precaution: Do not disconnect any stimulation cables during a session while the stimulator is switched on. Switch the stimulator off first. Always turn off the stimulator before moving or removing any electrodes during a session.

Precaution: Do not use electrodes with an active area less than 16 cm^2, as there will be a risk of suffering a burn injury. Caution should always be exercised with current densities more than 2mA/cm^2.

Precaution: Do not apply stimulation in the vicinity of metal. Remove jewelry, body piercings, buckles or any other removable metallic product or device in the area of stimulation. Never use the electrodes contra-laterally; i.e., do not use two pins connected to the same channel on opposite segments of the body.

Depending on the characteristics of the current, efficacy can be optimized in certain programs. When working with a muscle stimulation program (program involving muscle contractions, P1 or P2), it is important to place the negative electrode (connected to the black connector) on the motor point of the muscle.

To ensure the efficacy of the program, it is crucial to choose the right size electrodes (large or small) and correctly position these on the muscle group you want to stimulate. Therefore, always use the size of electrodes your clinician instructs you to use. When using the garment, always use the provided electrodes and electrode placements unless you have explicit instructions otherwise from your clinician. Use the Empi Phoenix Thigh Garment only with P1 and P2, **not** with P3 or P4.

6.4.1 Use of the Phoenix Thigh Garment

The Empi Phoenix Thigh Garment can be used as an accessory to help you position and hold the electrodes in place for the Endurance (P1) and Strength (P2) programs. Please refer to the Empi Phoenix Garment User Manual for proper use of the Empi Phoenix Thigh Garment with the Empi Phoenix device.

6.5 Stimulation Positions

Your body position during therapy will vary depending on the position of the electrodes, the muscle group you wish to stimulate, and the program you are using. Follow your clinician's instructions for body positioning. One commonly recommended position for Endurance and Strength (P1 and P2) programs for knee treatments is to be seated with your foot flat on the floor and your knee at a 90 degree angle to allow for isometric contractions. For P1 (Endurance) and P2 (Strength) programs, you should normally stimulate isometrically; this means that the extremities of the limb in which a muscle is being stimulated must be firmly fixed to prevent the movement that results from the muscle contraction. Consult your clinician for use of the device together with movements. For TENS and Edema programs (P3 and P4) position yourself as comfortably as possible.

Precaution: Never carry out an initial stimulation session on a person who is standing. The first five minutes of stimulation must always be performed on a person who is sitting or lying down. In rare instances, people of a nervous disposition may experience a vasovagal reaction. This reaction is connected with fear of the muscle stimulation as well as surprise at seeing one of their muscles contract without having intentionally contracted it themselves. A vasovagal reaction causes heart to slow down and blood pressure to drop, which can make you feel weak and faint. If this does occur, stop the stimulation and lie down with the legs raised until the feeling of weakness disappears (5 to 10 minutes).

6.6 Adjusting Stimulation Energies

When using the Endurance and Strength programs, the benefits of therapy are improved as the electrical intensity increases. Unless you have instructions from your clinician otherwise, you should increase the intensity of the Endurance (P1) and Strength (P2) programs until you get a strong muscle contraction. Please follow the Safety Information advice in Section 4 to avoid injury.

7. Operating Instructions

You are strongly advised to carefully read the Safety Information in Section 4 at the beginning of this manual prior to using your stimulator.

Precaution: Sudden temperature changes can cause condensation to build up inside the stimulator. To prevent this, allow it to reach room temperature before use.

7.1 Description of the Device

A. User Interface LCD

B. ON/OFF (Pause) button ⏻

C. Program Selection (Increase) button **P+**

D. Program Selection (Decrease) button **P-**

E. Channel 1 Intensity Increase/Decrease button ∧ ∨

F. Channel 2 Intensity Increase/Decrease button ∧ ∨

G. Channel 1 output connector

H. Channel 2 output connector

I. Remote switch input connector (hand switch is an optional accessory)

J. Belt Clip (removable)

K. Battery door to access the battery compartment. A label describing the programs is affixed to the battery door.

7.2 Kit Composition and Accessories

Accessory	Part Number	Quantity	Description
STANDARD INCLUSIONS – PHOENIX DEVICE			
Unit	199696	1	One Phoenix device
Lead wires	193057-100 (40” long)	2	Package of one leadwire assembly with red and black pins
Standard electrodes	199327-001	2	Package of four carbon cloth 2"x 2" StimCare electrodes*
Batteries	200045	1	Package of four rechargeable AA batteries
Battery charger	200047	1	Battery charger
Device pouch	235694	1	Carrying pouch for the device
Instructions for Use	360413	1	Phoenix Instruction for use
Quick Start Guide	802425	1	Quick start guide for the patient
DVD	802427	1	DVD
OPTIONAL PHOENIX THIGH GARMENT			
Phoenix thigh garment	235684	1	Garment
Garment connector	193075	1	Attaches device to garment
Garment electrodes	199695	2	Packets of one 6"x 3.5" and two 2.75" x 4" electrodes
OPTIONAL INCLUSIONS AVAILABLE UPON REQUEST			
Leadwires	193057-150 (60” long)	2	Package of one leadwire assembly with red and black pins
Dispersive pad	199501-001	1	Large 5"x 8" pad for Edema use
Bifurcated lead	700211-001	1	Split lead for Edema use
Hand switch	235693	1	Switch for manual stim activation

*Your clinician may request different electrodes.

7.3 Preparation

7.3.1 Insertion/replacement of the batteries

1. Remove the belt clip by disengaging one of the arms on the side of the device.

2. Remove the battery door by sliding it downward along the device.

3. Place the batteries as indicated on the bottom of the battery compartment. Note the polarity and the battery type. Use only IEC LR06 AA 1.5 V Alkaline or rechargeable AA NiMH 1.2 V batteries.

4. Close the battery door by sliding it upward until it clicks into place as shown. Make sure the battery door is fully engaged before switching on the device.

5. You may or may not use the belt clip, as you prefer.

6. Dispose of the old batteries in accordance with local and national regulations.

Remove the batteries from the Empi Phoenix device if it is not used for a prolonged period of time (e.g. more than 3 months).

7.3.2 Connection of the lead wires to the device

Always inspect the lead wires connection before using them. If any connection is damaged, do not use the lead wire and replace it.

1. Connect Channel 1 and Channel 2 lead wires into their respective socket as shown.

2. Make sure the lead wire is fully engaged by pressing the leadwire connector head firmly into the socket.

Correct

Incorrect

3. You may not need to insert Channel 2 lead wire, depending on the program and electrode configuration you are using. Consult your clinician for instruction on how to use the appropriate program and proper placement of the electrode (see also Section 6.4 of this manual).

4. To disconnect the lead wire, pull the lead wire connector head away from the connector. **Never** pull on the lead wire directly to remove it from the device, as this may damage the lead wire.

7.3.3 Placement and care of the electrodes

NOTE: This section applies to electrodes used with conventional leadwires. If you are using the Phoenix Thigh Garment, please follow the Garment and Garment Electrode instructions.

1. Peel off the electrodes from the plastic film and apply them on the appropriate body area. Follow your Clinician's recommendation and Section 6.4 for proper electrode placement. Always ensure the electrodes are fully in contact with the skin. If the adhesion of the electrodes is not good, use new electrodes.
2. At the end of the treatment, first disconnect the lead wires from the electrodes. Next, peel off the electrodes from the skin and place them back on the plastic film. Put them back into the plastic bag and reseal it.
3. Electrodes will eventually wear out. Check accessories regularly for signs of wear and replace as needed. Stop using electrodes if their bonding power becomes poor. Contact Empi to order additional electrodes.

   To maximize service life for electrodes:

   - Clean the skin application sites with mild soap water before attaching the electrodes. After cleaning, thoroughly rinse with water and dry the skin carefully.
   - Dry electrodes with poor adhesion can be reconditioned. See electrode packaging for complete instructions.
   - If you encounter contact with the skin or repeated open lead detection, replace the electrodes.
   - Remove electrodes by pulling on their edges. Do not pull on the lead wire.
   - After use, reattach the electrodes to their protective plastic film. Store the electrodes in their bags.
   - Store the electrodes in a cool place.
   - We recommend clipping excess hair from sites where electrodes will be applied. Trim the hair with scissors; do not shave.
   - Do not leave the electrodes attached to your skin for a prolonged period of time. Remove the electrodes after each use. To avoid skin irritations, apply the electrodes to different areas and clean the skin thoroughly after treatment. If you observe skin irritations, consult your Clinician and discontinue therapy until the irritation subsides.

7.3.4 Connection of the lead wires to the electrodes

Connect the pin end of the lead wire to the chosen electrode. Pay attention to the polarity shown in Section 6.4 and the indications given in Section 2.1.

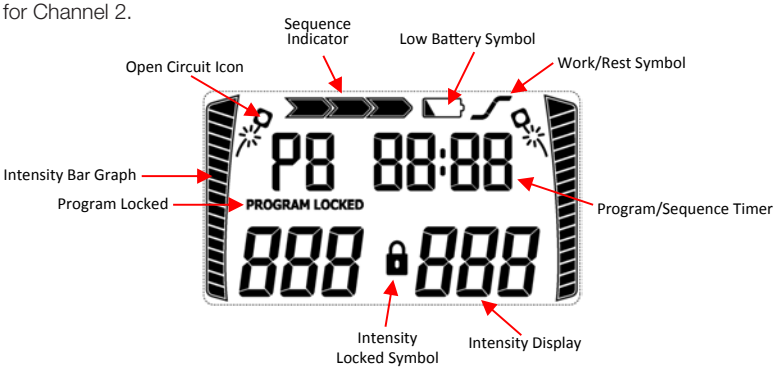
7.3.5 Use of the Empi Phoenix Thigh Garment Device (optional)

Please refer to the Empi Phoenix Thigh Garment User Manual for proper use.

7.4 Operation of the Device

7.4.1 LCD display

The Empi Phoenix device is equipped with a Liquid Crystal Display (LCD) to make the User Interface easy to use and understand, and to provide clear information about the on-going treatment. The following picture depicts the complete LCD with all its symbols. Intensity Display, Intensity Bar Graph, and Open Circuit Icon are on the left for Channel 1 and on the right for Channel 2.



7.4.2 Operation information

- You can interrupt therapy at any time with the ON/OFF ⏻ switch.
- If the stimulator is not used, it switches off automatically after approximately 5 minutes.
- When the therapy timer is activated, the device switches off automatically at the end of the programmed interval. The remaining therapy time is always indicated on the display.
- The program can only be changed when the intensity in both channels is 0.

7.4.3 Operating instructions

1. Turn on the device by pressing the ON/OFF ⏻ button. The software version will be displayed briefly.

2. The LCD will then automatically switch to the Program Selection Screen.

3. Use the Program Selection Increase **P+** and Decrease **P-** buttons to select the program prescribed by your healthcare provider. Change of program is possible only when both channel intensities are 0. The available programs are P1 (Endurance), P2 (Strength), P3 (TENS) and P4 (Edema). The list of programs is also mentioned on the battery door label.

The device might be locked into a pre-defined program selected by your Clinician. In this case, you cannot change the program selection and the Program Selection buttons are inactive. A corresponding text will appear below the program number.

4. The sequence indicator will indicate the number of sequences for each program. The program timer indicates the total duration of the program. Once you have selected the desired program, simply increase the intensities of the channels you want using the Increase Intensity buttons. For intensity strength information, refer to 6.6.
5. The intensity of each channel will be displayed both numerically and with a bar graph. Note that intensities of Endurance (P1) and Strength (P2) programs are expressed in Energy levels (max 520) while intensities of TENS (P3) and Edema (P4) programs are expressed in mA (max 100 mA).

7.4.4 Pause function

During a treatment, you can pause the treatment at any time by pressing the ON/OFF ⏻ button once. In this case, both intensities will drop to 0, the timer will stop, and the timer indicator will blink.

To resume the treatment, increase the intensities to the desired level. This will automatically resume the timer.

When you are in the Pause mode, you can also switch off the unit by pressing the ON/OFF ⏻ button a second time.

7.4.5 End of treatment

For all treatments except P3 (TENS), the timer will automatically finish the treatment. When the treatment is finished, intensities are automatically reduced to 0 and the timer indicator will flash with 00:00.

For the TENS (P3) program, the timer is unlimited, meaning that it does not automatically shut off after a set time. Stop the treatment after the time recommended by your healthcare provider by pressing the ON/OFF ⏻ button.

- Turn off the device by pressing the ON/OFF ⏻ button.

Disconnect the electrodes and the lead wires as indicated in section 7.3. Electrodes no longer fit for use can be disposed of with the normal domestic waste.

7.4.6 Use of the hand switch (optional)

The hand switch connects to the unit on the dedicated port:

The hand switch can be used to manually change the cycles of contractions/active-rest or turn the stimulation On and OFF.

- In a constant mode (P3, P4, warm up and cool down of P1 and P2), pushing the button will activate the stimulation while releasing it will bring all intensities to 0.
- In Work mode, pushing and releasing the button, respectively, will toggle between contraction and active-rest phases.

7.5 Meaning of Indicators

7.5.1 Intensity lock

If you do not adjust the intensities for 10 seconds, the intensities are automatically locked to avoid accidental intensity modification. When the intensity lock is on, the lock symbol appears next to the intensity displays. To unlock the intensities, press either of the Intensity Decrease ▼ buttons. You can then re-adjust the intensity.

7.5.2 Sequence indicator

The sequence indicator is the set of three chevron symbols on the upper middle of the screen. These symbols indicate when the program is in warm up (first chevron), treatment (second chevron), and cool down (third chevron) modes. Each chevron is filled as that portion of therapy occurs. For TENS (P3) and Edema (P4) treatments, there is only one sequence.

7.5.3 Work/rest indicator

The work/rest indicator is the curved line on the upper right of the screen. When the treatment is active, this indicator will show whether the therapy is in “work mode” (contraction) or “rest mode” (low frequency stimulation). During the “work mode”, the upper line of the symbol will blink. During the “rest mode”, the lower part of the symbol will blink. TENS (P3) and Edema (P4) treatments do not have a rest mode.

7.5.4 Timer indication

The timer indicates the remaining time of the active sequence. For the TENS program (P3), the timer indicator displays —:— as the program duration is unlimited, and does not automatically shut off after a set time. (To end a TENS program, press the ON/OFF ⏻ button twice.)

7.5.5 Low battery indicator

When the battery voltage drops below a predefined limit, the battery symbol appears.

If you are in the middle of a treatment, you may complete your treatment and change the batteries before starting a new treatment. Don’t start a new treatment without changing the batteries if the low battery symbol is present. Please refer to section 7.3.1 for proper battery replacement.

7.5.6 Open circuit icon

The Open Circuit icon appears when the resistance between the device and the skin is too high. The symbol appears next to the channel bar graph where the open circuit has been detected.

The Open Circuit icon might appear due to a poor electrode attachment or an interrupted electric circuit. When the electric circuit is interrupted, the intensity drops to 0 and the program is paused. In this case check whether the electrode lead wire is correctly connected to the device and whether the electrodes are properly connected.

8. Troubleshooting

If an error screen appears while you are using the device, write down the error code displayed and contact Empi's Repair Department at 800.862.2343.

Problem	Possible cause	Solution
The stimulator is not working	Batteries	A. Make sure the batteries are properly installed. (Check polarity markings). B. Make sure the battery contacts are clean.
	Device not answering	If the device is ON, but does not respond to pressing the key pad buttons: A. Detach all patient lead wires from the device; B. Remove batteries from the device; C. Wait 10 seconds; D. Re-insert batteries and resume treatment.
	Low batteries	If the Low Battery Indicator is visible, replace both batteries.
	Bad connection	If the device is on, the intensity bar graphs and controls are on, and you feel no stimulation, check and verify the connection of lead wires and electrodes.
	Lead wire or electrode defective	If the device appears to be functioning , and there is no stimulation, replace the lead wires and/or electrodes.
Display does not come on	Battery	A. Try fresh batteries. B. Ensure batteries are inserted correctly. See instructions for proper placement.
	Battery contact failure	A. Check contacts are in place. B. Check contacts are not broken. C. Check contacts are not pushed in. They should make contact when battery is inserted.
Weak stimulation with fresh batteries	Electrodes dried out	Replace electrodes.
	Electrode placement	Make the electrodes at least 2" apart.
Stimulation stops with fresh batteries	Poor electrode contact	Reapply electrodes, secure firmly. Electrodes must be a minimum of 2" apart.
	Damaged or worn electrodes or lead wires	Replace.
Stimulation weakens within minutes of starting treatment with fresh batteries	This is a normal body adaptive process	Increase the amplitude (intensity).

Problem	Possible cause	Solution
Stimulation is uncomfortable	Amplitude (intensity) is too high	Decrease amplitude (intensity).
	Electrodes are too close together	Reposition the electrodes. Electrodes must be a minimum of 2 inches apart.
	Damaged or worn electrodes or leadwires	Replace.
	Ensure proper program is being used	A. Refer to section 6.1 for a description of the Programs B. Contact clinician if discomfort persists.
Stimulation is ineffective	Improper electrode placement	Reposition electrodes. Electrodes must be a minimum of 2 inches apart.
	Unknown	Contact clinician.
Stimulation only felt on one electrode	Improper electrode placement	A. Reposition electrodes. Electrodes must be a minimum of 2 inches apart. B. Replace electrodes.
Stimulation on one channel (side) only	Electrodes: A. Worn or damaged B. Improper placement	A. Replace. B. Reposition electrode. Electrodes must be a minimum of 2 inches apart.
	Leadwires worn or damaged	Replace.
	Component failure	Try each leadwire independently in each channel. If there is no output on either channel the leadwire is defective and should be replaced. If there is output on one channel only, a component may have failed. Call the Repair Department.
Intermittent Output	Leadwires	A. Verify connection is secure. B. Turn down the intensity. Rotate leadwires in socket 90 degrees. If still intermittent, replace leadwire. If still intermittent after replacing the leadwire, a component may have failed. Call the Repair Department.
	Intermittent program in use	Some programs will seem intermittent. This is expected. Refer to section 6.1 for a description of the Programs.
Stimulation is not producing the usual sensation	Settings and Electrodes positioning	A. Check that all the settings are correct and ensure the electrodes are positioned properly. B. Change the positioning of the electrodes slightly.

To self-test for any of the above, perform the following steps:

1. Place new batteries in the device.
2. Verify the device is off.
3. Insert one new lead wire into two new electrodes.
4. Place the new electrodes on your forearm as shown in Figure A.
5. Insert the lead wire in Channel 1.
6. Turn your device on.
7. Select program P3 (TENS). This is a continuous treatment program.

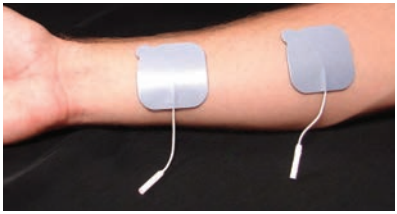


Figure A

8. Slowly increase the amplitude (intensity) until you can feel it. If you do not get any sensation, lower the amplitude (intensity) to zero and rotate the lead wire 90 degrees. Slowly increase the amplitude (intensity).
9. If there is no sensation, call the Repair Department.
10. If sensation is felt, even if weak, the device is working properly. You may need to reposition the electrodes or contact your clinician.
11. Repeat Steps 1 through 10 for Channel 2.

9. Device Maintenance

9.1 Service

Please contact Empi at the numbers below if you need assistance setting up, using, or maintaining the Phoenix System or to report any unexpected operation or events.

For clinical questions, contact the Professional Services Department at 800.328.2536 or 651.415.9000.

If any component of the Phoenix System is not functioning properly or requires servicing, contact the Empi Repair Department at 800.862.2343 or 605.874.6965.

When returning any products, please include your name, address, phone number and a description of the problem.

Return to: Empi
Attn: Repair Department
47492 SD Hwy 22
Clear Lake, SD 57226 USA

9.2 Cleaning and Calibration

Clean using a damp cloth or soft cloth and an alcohol based, solvent-free cleaning product. Use only a minimum amount of liquid when cleaning the Empi Phoenix device. Allow the Empi Phoenix device to completely dry before use.

Do not sterilize the stimulator. Do not immerse in liquids.

Your stimulator does not require calibration. Each Empi Phoenix stimulator is tested prior to distribution. Its characteristics do not vary under normal conditions.

9.3 Repair

There are no user serviceable parts inside the device. If the device appears to be non-functional, contact your clinician, or contact Empi directly at 800.862.2343.

Do not attempt to repair the stimulator or any of its accessories. Never dismantle the Empi Phoenix device because of risk of electric shock. Empi, Inc. declines all responsibilities for any damages or consequences resulting from unauthorized attempts to open, modify, or repair the stimulator. This may only be done by persons or repair services authorized by Empi, Inc.

9.4 Operating Conditions

The Empi Phoenix device should be operated in temperatures between 50°F and 104°F (10°C and 40°C), atmospheric pressures between 50 and 106 kPa, and relative humidity between 30% and 75%.

9.5 Transportation and Storage Conditions

The Empi Phoenix device should be transported and stored in temperatures between -40 °F and 158 °F (-40 °C and 70 °C), atmospheric pressures between 50 and 106 kPa and relative humidity between 10% and 90%.

9.6 Expected Life and Disposal

The Empi Phoenix device is expected to provide at least seven years of normal use.

If you are renting the Empi Phoenix device, please return it to Empi when you no longer need it for therapy.

The Empi Phoenix device is electronic equipment and may include substances that can damage the environment. DO NOT dispose of the device in municipal waste. Please deliver the device to a suitable collection point for recycling of electronic equipment or contact the Empi Repair Department (see Service section) to return it for recycling. By doing so, you will be contributing to the safeguarding of natural resources and health.

Please dispose of batteries in compliance with relevant national or state regulatory requirements. Do not puncture. Do not dispose in fire or incinerate.

When the electrodes no longer stick well to your skin, dispose of them in a receptacle out of reach of children and pets.

10. Ordering Information

To order replacement electrodes, leadwires, or other accessories for your Empi Phoenix device, contact Empi Patient Care at 800.328.2536, ext. 8455. See Section 7.2 for Empi Phoenix Kit components.

11. Clinician Only Section

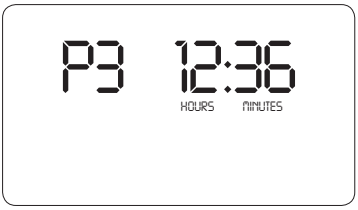
This section is only intended for clinicians and the functions described in this section should not be operated by the patient.

11.1 Compliance Monitoring

The Empi Phoenix device is equipped with a compliance monitoring system. This allows you to monitor the usage of the device by your patient between visits.

To access the compliance screen, simultaneously and continuously push on the Program Decrease **P-**, Left Decrease Intensity ▼ and Right Decrease Intensity ▼ buttons while you are in the Program Selection mode.

In the compliance screen, you will see the total time spent in each of the programs by switching between the different programs (for this, use the P- and P+ keys).



Note: Timer indicates hours and minutes instead of minutes and seconds when you are in the Compliance screen.

Compliance counters reset

To reset the compliance counters, press continuously and simultaneously for more than 3 seconds the Program Decrease **P-**, Left and right Decrease intensity ▼ (same key combination as to access the compliance screen).

To exit the compliance screen, switch Off the device by pressing the ON/OFF ⏻ switch.

11.2 Program Lock

You can lock the Empi Phoenix into a specific program. This will limit the use of the device in this specific program without the possibility for the patient to access any other program.

To lock the device

1. Select the program you want to lock the device into when you are in the Program Selection screen.
2. Push continuously and simultaneously on the Program Increase P+, Program Decrease P- and Right Decrease V buttons.
3. The Program Lock symbol will appear. The lock setting is kept in memory when you turn off the device.

To unlock the device

Push continuously and simultaneously on the Program Increase P+, Program Decrease P- and Right Decrease V buttons until the Program Lock symbol disappears.

11.3 Ordering Information for Clinicians

To order the Empi Phoenix device for your patients, contact either your local Empi/DJO Global representative or Empi Clinic Services at 800.325.5663.

12. Limited Warranty

Warning

While, in the opinion of Empi, Inc. the use of the Empi Phoenix ("the Product") has met with some success, Empi, Inc. makes no warranties to the purchaser as to the effectiveness of the product.

Warranty

A. Empi, Inc. warrants to the initial Purchaser ("Purchaser") (and to no other person) that the Product (with the exclusion of accessories such as chargers, rechargeable batteries, electrodes, lead wires, tape adhesive patches and electrode cream) and the component parts thereof, distributed or manufactured by Empi, Inc., shall be free from defects in the workmanship and materials for three years from the initial date of purchase from Empi, Inc. (the "Warranty Period").

B. Accessories including, but not limited to, chargers, rechargeable batteries, electrodes, lead wires, tape adhesive patches and electrode cream are excluded from the Warranty and sold "AS IS" because their structure is such that they may be easily damaged before or during use.

Limitation of Liabilities and Disclaimer or Warranties

A. Empi, Inc.'s sole obligation in the case of any breach of its warranties set forth in Paragraph A in the Warranty section above, shall be, at Empi, Inc.'s option, to repair or replace the Product without charge to Purchaser or to refund the purchase price of the Product. In order to recover under this Warranty, Purchaser must send Empi, Inc. written notice of the defect (setting forth the problem in reasonable detail) prior to expiration of the Warranty Period and within 30 days of discovery of the defect. Upon Empi, Inc.'s written request and authorization, Purchaser shall return the Product to Empi, Inc., freight and insurance prepaid, for inspection. Notice and return shipment shall be sent to Empi, Inc. at 47492 Hwy. 22, Clear Lake, South Dakota 57226, USA, or to an Empi, Inc. Authorized Service Center. To locate the appropriate Service Center outside of North America, or to request shipment approval, contact Empi, Inc. directly. Empi, Inc. will not be responsible for damage due to improper packaging or shipment. If Empi, Inc. determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Empi, Inc. will refund to the Purchaser, the purchase price for the defective product, or return the repaired Product or a replacement thereof to Purchaser, the purchase price for the defective product, or return the insurance prepaid, as soon as reasonably possible following receipt of the Product by Empi, Inc.. Empi, Inc. determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, Empi, Inc. will return the Product to the Purchaser, freight and insurance billed to the Purchaser.

B. This Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized employees or agents of Empi, Inc. or which has been subjected to misuse, abuse, neglect, damage in transit, accident or negligence.

C. Except as provided in paragraph A, the product is being sold on an as is basis, all accessories are sold as is, and the entire risk as to the quality and performance of the product is with purchaser. The warranty provided in paragraph A is intended solely for the benefit of the initial purchaser and Empi, Inc. disclaims all other warranties, express or implied including, but not limited to, any implied warranties of merchantability and fitness for a particular purpose; provided, however, that notwithstanding the foregoing sentence, in the event an implied warranty is determined to exist, the period for performance by Empi, Inc. thereunder shall be limited to the lifetime of the initial purchaser. No employee, representative or agent of Empi, Inc. has any authority to bind Empi, Inc. to any affirmation, representation or warranty except as stated in this written warranty policy.

D. Empi, Inc. shall not be liable to any person for any direct, indirect, special, incidental or consequential damages, lost profits or medical expenses caused by any defect, failure, malfunction or otherwise of the product, regardless of the form in which any legal or equitable action may be brought against Empi, Inc. (e.g. contract, negligence or otherwise) the remedy provided in paragraph A above shall constitute purchaser's sole remedy. In no event shall Empi, Inc.'s liability under any cause of action relating to the product exceed the purchase price of the product. This Warranty gives the purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how long an implied warranty lasts, so the above limitation may not apply to the Purchaser.

13. Technical Specifications

Standard Measurement Conditions

- Temperature - 25°C +/-5°C
- Load Range - 500 Ohms - 1 kOhms
- Power Supply - 3.0V DC +/-10%

Output Waveforms

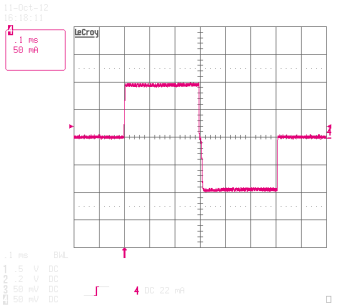
The following are theoretical standard measurement output current across purely resistive loads at maximum intensity setting. Pulse Width and current measured as shown across 1kOhm loads. These measurements are also valid on a 500 Ohm load, as the Phoenix is a current controlled device. Any load between 500 Ohms and 1 kOhm will not affect the output measurements. Your output may vary depending on parameter settings.

P1 Endurance Program

Maximum Intensity: 520 Energy levels, corresponding to 100 mA intensity and 300 µs pulse width

Zero net DC component

Maximum charge per pulse: 2 x 30 µC

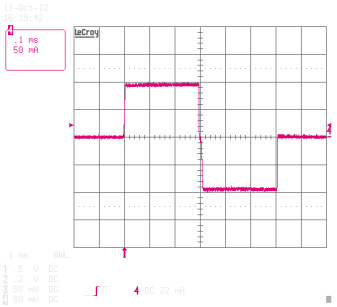


P2 Strength Program

Maximum Intensity: 520 Energy levels, corresponding to 100 mA intensity and 300 µs pulse width

Zero net DC component

Maximum charge per pulse: 2 x 30 µC

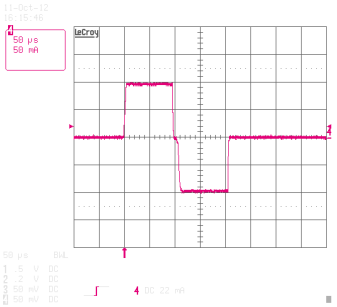


P3 Modulated TENS Program

Maximum Intensity: 100 mA

Zero net DC component

Maximum charge per pulse: 2 x 8 µC

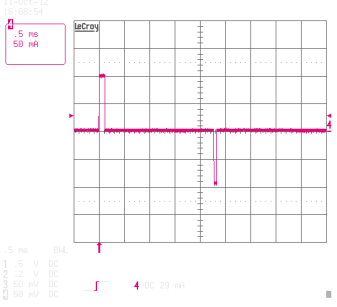


P4 Edema Program

Maximum Intensity: 100 mA

DC component: 266 µA, independent of the set intensity as long as the set intensity is above 4 mA.

Maximum charge per pulse: 7.2 µC for the positive pulse and 6 µC for the negative pulse



Low Voltage Indication

- Indicator Threshold: 2.3 Volts (typical)
- Shutdown Voltage: 1.95 Volts (typical)
- These voltages may be tested under NO load condition.

Fuse Characteristics

6V, 1.5 A, Resettable, breaking capacity 3A

Physical Characteristics

- Size (without belt clip): 5.4” x 2.6” x 1.2”
- Weight (with batteries and belt clip): ~ 6 ounces
- Operational Temperature: 10°C to 40°C
- Humidity (maximum): 75% RH

EN 60601-1 Classification

- Type BF Applied Part
- Internally powered only
- Protection against ingress of particles and liquids: **IP22**
- Continuous operation
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

14. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

- The Empi Phoenix device needs special EMC precautions and must be installed and started according to the EMC information supplied in this manual.
- Portable and mobile RF communications equipment could affect the Empi Phoenix device. For example mobile phones can affect the Empi Phoenix device. Avoid placing a mobile phone is direct proximity to the Empi Phoenix device.
- Warning: The use of accessories, other than those recommended by the manufacturer, may result in stronger emissions or reduce the immunity of the Empi Phoenix device.
- Warning: The Empi Phoenix device should not be used beside or stacked on top of any other equipment. If you must use it side by side or on top of another system, you should check that the Empi Phoenix device works properly in the chosen configuration.
- Meeting the emissions levels shown in the first table is considered to be essential performance of the Empi Phoenix device.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
Empi Phoenix is intended for use in the electromagnetic environment specified below. The customer or user of the Empi Phoenix should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guide**
RF emissions CISPR 11	Group 1	The Empi Phoenix uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Empi Phoenix is suitable for use in any establishment, other than a private dwelling or a place connected directly to the low voltage mains supply which powers residential buildings.
Harmonic emissions IEC 61000-3-2	Not applicable, battery powered	
Voltage fluctuations/ emission oscillations IEC 61000-3-3	Not applicable, battery powered	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
Empi Phoenix is intended for use in the electromagnetic environment specified below. The customer or user of the Empi Phoenix should assure that it is used in such an environment			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment - recommendations**
Electrostatic discharge (DES) CEI 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not Applicable – Battery powered Not Applicable – signal lines less then 3 meters	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable – Battery powered	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not Applicable – Battery powered	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Phoenix requires continued operation during power mains interruptions, it is recommended that the Empi Phoenix be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Empi Phoenix is intended for use in the electromagnetic environment specified below. The customer or the user of the Empi Phoenix should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - recommendations
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the Empi Phoenix device, including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distances** $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and where *d* is the recommended separation distance in metres (m). The field strength from fixed RF transmitters, as determined by an electromagnetic survey [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and at 800 MHz ,the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Empi Phoenix device is used exceeds the applicable RF compliance level above, the Empi Phoenix device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Empi Phoenix device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE EMPI PHOENIX

The Empi Phoenix is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Empi Phoenix can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Empi Phoenix as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distances according to frequency of the transmitter** **m**		
	From 150 kHz to 80 MHz	**From 80 kHz to 800 MHz**	**From 800 MHz to 2.5 GHz**
W	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.79	3.79	7.27
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is modified by absorption and reflection from structures, objects and people.

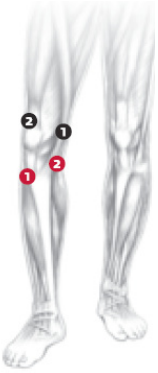
15. Additional information on Electrode Placement for Knee Rehabilitation

In the absence of direction from a clinician on electrode placement, use the following electrode placement guidelines for knee rehabilitation if using the Empi Phoenix device with direct leadwires and not with the Empi Phoenix Thigh Garment.

NMES Programs – P1 (Endurance) and P2 (Strength):

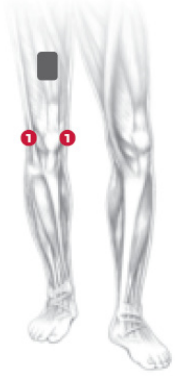
1. Place the Channel 1 black lead over the Vastus Medialis Oblique (VMO). The VMO is a muscle in your quadriceps that typically sits just above and inside your kneecap.
2. Place the Channel 2 black lead over the Vastus Lateralis (VL). The VL is the muscle in your quadriceps that sits about two inches further up the leg from the VMO but on the outside of the leg.
3. Place the Channel 1 red lead in the middle of your quadriceps (thigh).
4. Place the Channel 2 red lead in the middle of the upper part of your quadriceps (thigh).
5. To use on a portion of the body other than the knee/quadriceps, consult a clinician.

TENS Program – P3 (High Frequency TENS):



1. Place the Channel 1 black lead over the upper inside portion of your knee.
2. Place the Channel 2 black lead over the upper outside portion of your knee.
3. Place the Channel 1 red lead over the lower outside portion of your knee.
4. Place the Channel 2 red lead in the lower inside portion of your knee.
5. You should position the electrodes so they surround the area of pain.
6. To use on a portion of the body other than the knee, consult a clinician.

EDEMA Program – P4 (Pulsed Direct):



1. To use the Edema program, you will need the bifurcated lead and dispersive electrode. If you did not receive these items, contact Empi Customer Service.
2. Plug the bifurcated lead into the red leadwire on Channel 1.
3. Place the electrodes on the bifurcated lead on the inside and outside of the affected joint.
4. Attach the large dispersive electrode to the black lead on Channel 1 and place over the upper thigh.
5. To use on a portion of the body other than the knee, consult a clinician.

16. Quick Start Guide

Read full instructions before using the device.

1. Insert batteries into the device and replace the battery cover.

2. Place electrodes or garment following healthcare provider's instructions. Insert the wire from the garment (if using the garment) or electrode leadwire (if not using the garment) by pressing the attachment into the port on the device.

3. Turn the device on by pressing the ⏻ button.

4. Select the therapy (P1 Endurance, P2 Strength, P3 TENS or P4 Edema) prescribed by your clinician by pressing the **P+** or **P-** button.

5. Adjust intensity to desired level by pressing the ∧ and ∨ buttons for channels 1 and 2. You must select your program before turning up the intensity. Once the intensity is increased, the program will be locked.

NOTE: P1 and P2 begin with a two-minute Warm-Up phase, which will count down on the screen. The Warm-Up phase will cause your muscles to twitch but not contract. Set the device intensity to a comfortable level during Warm Up.

Once the Work Phase begins you can adjust the intensity further. P1 and P2 finish with a Cool Down phase. Refer to the Section 6.1 of this manual for a full explanation of these programs.

REF 199696 Phoenix Kit

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